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(54) A PROSTHETIC APPLIANCE

(71) We, COLORADO STATE UNIVERSITY FOUNDATION, of Colorado State University, Fort Collins, County of Larimer, State of Colorado, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a prosthetic appliance and, more particularly, to a prosthesis in the form of an artificial vertebra to be used singly or in combination to bridge the gap left in the spinal column when one or more of the natural vertebrae have to be removed because they are deseased, broken or malformed.

Occasions sometimes arise in the treatment of the higher vertebrates, both man and animal, when it becomes desirable to remove one, and possibly, several, vertebrae from the spinal column. Removal of a diseased section may, for example, be necessary to check the spread of the disease to adjacent portions of the spinal column and the surrounding tissues. Accidents and birth defects may, likewise, produce conditions that necessitates removal of part of the vertebral column.

Notwithstanding the need for some form of prosthesis to replace completely one or more vertebrae, up to the present time none has been available. Accordingly, both the surgeon and veterinarian have been forced to leave some portion of the natural diseased or broken vertebra in the body to provide a bridge or link between adjoining healthy vertebra on either side thereof. In many instances, this is a highly unsatisfactory solution and may, in the case of cancerous or otherwise diseased bone, enable the disease to spread.

The present state of the art is such that little can be done insofar as substituting a prosthetic appliance for the centrum, or body portion, of the vertebra, the latter being required to maintain the continuity of the vertebral column. About all that can be done is to bridge across a broken neural spine and, in rare instances, substitute a metal arch bridging the natural neural spines for an entire neural arch.

According to the present invention there is provided a prosthetic appliance for insertion into the gap left in the spinal column of a higher vertebrate following removal of one or more natural vertebrae therefrom, comprising a prosthetic unit, for each removed natural vertebra, the, or each, said unit comprising two elements adapted to be secured together, one face of one element which contacts a face of the other element of the same unit containing a trough for the reception therein of the vertebrate's spinal cord, one of said elements of the or each unit having a stem-portion corresponding to the neural spine of a natural vertebra, first connecting means attached to said stem-portion of the unit, or to the stem portions of each end unit of a series of pivotally interconnected units, for attachment to the neural spine of the natural vertebrae adjacent thereto, and second connecting means on a centrum portion of the other element of said unit or on the centrum portion of the other element of each unit for attachment to the centrum portion of the natural vertebra or unit on each side thereof, said first and second connecting means being operable for holding the natural vertebra on each side of the gap in fixed relation to the unit, or of the series of interconnected units, of said appliance.

The present invention also provides a prosthetic appliance for insertion into the gap left in the spinal column of a higher vertebrate following removal of one or more natural vertebra therefrom, comprising a prosthetic unit for each removed natural vertebra, the or each said unit comprising a body element (as defined hereinbelow) having a substantially flat surface that has a substantially semi-cylindrical trough extending therecross, a substantially Y-shaped element having a stem-portion merging at one extremity into divergent leg-portions for fastening on to the surface portions of the body element of the same unit on opposite

[*Price 25p*]

sides of the trough to cooperate with the body element in defining a passage for the loose reception therein of said vertebrate's spinal cord, first connecting means attached to the stem-portion of the Y-shaped element or to the stem-portions of the Y-shaped elements of the end units of an interconnected series thereof for attachment to the neural spine of the natural vertebrae adjacent the gap, and second connecting means attached to the body element, or to the body elements of the end units of said series thereof, for attachment to the centrum of the adjacent nautral vertebrae or vertebra, said first and second connecting means being cooperable with one another for holding the natural vertebra on each side of the gap in fixed relation to the unit, or adjacent unit of the series of units of said appliance.

The expression body element as used herein means that element of a unit or each unit which in use lies on the forward or inner side of the unit with respect to the body of the patient.

These features of the invention will be apparent from the following description of several forms of the prosthetic appliance which are given by way of example and with reference to the accompanying drawings, in which:

Figure 1 is a side elevation showing a single unit prosthetic appliance, formed by an inverted Y-shaped element and a body element attached in place between two natural vertebrae of a higher vertebrate;

Figure 2 is an end elevation of the prosthetic appliance by itself, portions of the inverted Y-shaped element having been broken away and revealed in section;

Figure 3 is a section taken along the line 3—3 of Figure 1;

Figure 4 is a top plan view of the appliance;

Figure 5 is a side elevation showing an appliance having one unit of the type revealed in Figures 1—4 used in conjunction with two slightly modified units to bridge a gap left upon removal of three adjoining natural vertebrae, a portion of one of the modified units having been broken away and shown in section;

Figure 6 is a bottom plan view of one of the modified units having a corner broken away and shown in section to reveal the interior construction;

Figure 7 is a side elevation similar to Figure 5 except that all three of the prosthetic units have been further modified to eliminate a rigid bridge and accept as a substitute therefor a springable hinge member that leaves the joint articulate;

Figure 8 is a section taken along line 8—8 of Figure 7; and

Figure 9 is a longitudinal section taken along the centerline of the Figure 7 body portions, the Y-shaped elements and connectors having been removed therefrom.

Referring now to the drawings for a detailed description of the present invention and, initially, to Figures 1—4, inclusive, for this purpose, reference numeral 10 has been employed to designate the phosthetic appliance in a general way and it will be seen to include an inverted generally Y-shaped element 12 detachably connected to a body-forming element 14 that has a semi-cylindrical trough 16 cut in its connecting surface 18 that, when joined to the divergent arms 20 of the Y-shaped element, cooperates therewith to define a cylindrical bore 22 adapted to receive the patient's spinal cord. As aforementioned, the divergent arms 20 of the Y-shaped member 12 function in much the same manner as the neural arches 24 of the patient's natural vertebrae that have been generally referred to by reference number 26; whereas, the stem portion 28 of said member takes the place of the neural spine 30 of the real bone. Body 14 of the prosthesis, on the other hand, replaces the centrum 32.

Elements 12 and 14 of the appliance are both preferably fabricated from some type of plastics material compatible with the internal tissues and bone of the body, several such materials being commercially available for use in the fabrication of prosthetic appliances. The material must, of course, be non-toxic, able to withstand the compression and bending loads to which a vertebrate's spine is subjected without breaking, and be workable through either machining or direct moulding techniques to produce a smooth surface which will not chafe or otherwise irritate the patient's spinal cord or the pads of cartilaginous tissue that separate same from the adjacent natural vertebrae. Thermoplastic vinylidene fluoride manufactured by Pennsalt Chemicals Corporation and marketed under the Trade Mark "Kynor" has proved quite satisfactory although there are probably several other materials that will do as well.

Dimensionally, the prosthetic device of the present embodiment closely approximates in overall height, width and thickness that of the vertebra it is to replace although, for a given animal species, these dimensions remain much the same so that the units can be manufactured on standard sizes. The various screws, nuts and connecting braces which will be described presently may also be fabricated from plastics materials although, from the standpoint of strength, it is desirable to make them from metal. Stainless steel, is satisfactory for this purpose although these elements are preferably made from a special steel alloy containing chromium, molybdenum and nickel sold under the Trade Mark "Vitalium" that is widely used in the fabrication of metal fittings for internal applications.

The Y-shaped element 12 is joined to the body portion 14 by means of four screws 34 (Figure 3) that pass into countersunk threaded openings 36 that extend from the arms 20 down into the body alongside spinal cord passage 22. The body must, of course, be passed in front of the patient's spinal cord into the space left vacant by removal of the natural vertebra before the arms of the Y-shaped element can be screwed thereto from the back through an incision made for this purpose. In those instances where the centrum 32 remains intact and only the neural arch and spine must be replaced. Y-shaped element 12 may be screwed directly to the centrum after the latter has been separated from the neural arch.

The body 14, in the particular form illustrated in Figures 1—4, has a pair of integrally-formed ears 38 projecting longitudinally in transversely-spaced relation from both ends thereof adapted to lap the centrum 32 of the adjacent natural vertebrae to which they are fastened by screws 40. As revealed most clearly in Figures 2 and 4, the opposed inside surfaces of the ears 38 are curved to conform with the shape of the natural centrum to which they are attached.

The stem portion 28 of the Y-shaped element 12 is provided with an elongated vertical slot 42 adapted to receive a screw fastener 44 that attaches a metal brace 46 to one side or, as shown, to each of the opposite side thereof. As shown in Figure 1, braces 46 include a plurality of apertures 48 to receive the screws 44 and are slightly curved. In the form shown in Figure 1 where the prosthetic appliance is used to bridge the gap left upon removal of only one natural vertebra, the braces are fastened on opposite sides of the stem 28 at approximately their mid-point. The extremities thereof thus project longitudinally beyond the stem in position to lap the adjacent neural spines 30 of the natural vertebrae in much the same manner as the ears 38 of the body 14 lap the centrum. These extremities are fixedly attached to the spines by screws 50 that pass through holes drilled in the latter.

As shown in Figure 1, the connection thus formed is a rigid one and no hinged or articulate movement takes place between the artificial vertebra and the adjacent natural vertebrae. Slot 42 merely makes it possible to raise and lower each brace 46 so that its extremities are properly located to be fastened onto the adjacent spines. The resulting rigid connection is much the same as would occur if two or more of the patient's natural vertebrae were fused, the latter being a fairly common surgical procedure for back injuries.

Next, reference will be made to Figures 5 and 6 wherein a slightly modified structure has been shown by means of which two or more missing natural vertebrae may be replaced by artificial ones. The prosthetic device 10*a* as shown on the left is much the same in construction as the one identified by numeral 10 in the previously-described Figures. The inverted Y-shaped element 12 is substantially identical except that it has slightly different dimensions. Each brace 46*a* is straight and shorter but performs the self-safe function as a brace 46, namely, to rigidly fasten the appliance 10*a* to the adjacent natural vertebra 26. The body 14*a* has, however, been modified slightly in that the ears 38*a* on the right-hand end thereof that fasten on to the second of the three prosthetic devices 10*b* are straight and parallel to one another like those shown in Figure 6 rather than being curved to fit the centrum as are the ears 38 on the left-hand end of the unit 10*a*.

The middle unit of the three (10*b*) again carries the identical Y-shaped element 28 but has a further modified base 14*b*. This modification, however, comprises nothing more than the elimination of the ears 38 from the left hand end of the unit 10*a* and substituting therefor sockets 52 adapted to receive the parallel ears 38*a* for limited pivotal movement about screw pivot 40.

The third unit of the three (10*c*) on the right-hand end of the assembly is still different in that the base 14*c*, instead of being equipped with the parallel ears 38*a* as is the middle element 10*b* has the curved ears 38 to fit the spectrum of the natural vertebrae. In all other respects, unit 10*b* and 10*c* are identical and the latter fastens on to the adjacent natural vertebra with modified braces 46*a* in the same manner as unit 10*a* to form a rigid connection therewith. While not illustrated, it is obvious that a unit like 10*a* could be used on both extremities of the assembly. This would necessitate altering the form of the middle unit 10*b* slight by replacing the ears 38*a* with sockets 52 and fitting the ears 38*a* on the unit 10*a* therein. Obviously, the above-described construction would be simpler than that illustrated because only two, rather than three, different forms of unit would be required. From another standpoint, however, the assembly shown in Figure 5 is preferred, namely, because it is adaptable for use in any situation requiring a chain of two or more artificial prosthetic vertebrae while the one described previously is limited to a three unit assembly. For example, in the construction shown, unit 10*a* can be connected directly to 10*c* eliminating 10*b* altogether and producing a two-unit chain. On the other hand, several units like 10*b* can be linked together between a 10*a* and 10*c* unit to form a longer chain where needed.

The remaining feature of the modification of Figures 5 and 6 that requires description

is arch 54. Two such arches 54 are fastened at their midpoints through elongate central slot 56 to slot 42 in the stem 28 of the middle unit 10*b* in the same manner as braces 46 in Figure 1. The extremities of these arches are similarly attached to the stems 28 of units 10*a* and 10*c* on opposite sides thereof through elongate end slots 58. By tightening fastener 44 in the central slot 56 so as to prevent any relative movement between the arches 54 and the middle appliance while leaving the screws a little loose that pass through the end slots 58, limited articulated movement between the end units 10*a* and 10*c* along with the natural vertebrae rigidly connected thereto and middle unit 10*b* is possible. If one were to make all of the aforementioned connections rigid, no less than five vertebrae (2 natural and 3 artificial) would be fused together and, perhaps, limit the patient's freedom of movement unduly.

Finally, with reference to the remaining Figures of the drawing, specifically Figures 7, 8 and 9, a further modified three-unit assembly has been shown wherein the metal arches 54 have been eliminated altogether and the bases 14*d*, *e* and *f* of the altered units 10*d*, *e* and *f* modified to include provision for carrying an elongate spring member 60. With the exception of the fact that units 10*d* and 10*f* have their bases modified to include a slightly frusto-conical socket 62 adapted to receive the extremities of spring member 60 in spaced parallel position beneath opening 22, these elements are identical to the previously-described members 10*a* and 10*c*, respectively as is their manner of connection to the adjacent natural vertebrae. Likewise, middle unit 10*e* corresponds closely to unit 10*b* except that the former has an opening 64 therethrough adapted to loosely receive the middle section of spring element 60. Specifically, opening 64 comprises. two opposed frusto-conical counterbores that intersect at the center of body 14*e* and flare as they emerge through the ends in axial alignment with the frusto-conical sockets 62.

The frusto-conical sockets and frusto-conical counterbored opening produce oblique frusto-conical surfaces wherein the elements thereof that lie closest to the pivots 40 are all colinear and tangential to the spring member 60 when the segments of the appliance occupy the straight line relation shown in Figure 9. Any flexion in a direction to open the gap 66 between the segments will, of course, be immediately resisted by the spring which biases them back to their straight line relation. Now, when the segments are flexed in the opposite direction to close gap 66, the elements of the frusto-conical surfaces diametrically opposite those previously mentioned assume a colinear relationship and lie tangential to the spring element. Thus, the latter type of flexion takes place independently of the spring which does not bend or otherwise resist such movement. For purposes of illustration, the slope of these frusto-conical surfaces has been exaggerated in Figure 9 because, as shown, with the Y-shaped members mounted atop the bases, the gap would close before the elements in the frusto-conical surfaces assumed a coinlear relation.

It will be readily apparent that the embodiments of Figures 5 and 7 can be modified to form a 'two-unit' appliance by omitting the intermediate unit and interconnecting the end units, the arches 54 or spring member 60 being shortened accordingly. Similarly the appliance could be extended by introducing at least one additional intermediate unit and connecting it to lengthened arches or a spring lengthened spring member in the same manner as the existing intermediate unit.

WHAT WE CLAIM IS:—

1. A prosthetic appliance for insertion into the gap left in the spinal column of a higher vertebrate following removal of one or more natural vertebrae therefrom, comprising a prosthetic unit for each removed natural vertebra, the, or each, said unit comprising two elements adapted to be secured together, one face of one element which contacts a face of the other element of the same unit containing a trough for the reception therein of the vertebrate's spinal cord, one of said elements of the or each unit having a stem portion corresponding to the neural spine of a natural vertebra, first connecting means attached to said stem-portion of the unit, or to the stem-portions of each end unit of a series of pivotally interconnected units, for attachment to the neural spine of the natural vertebrae adjacent thereto, and second connecting means on a centrum portion of the other element of said unit or on the centrum portion of the other element of each unit for attachment to the centrum portion of the natural vertebra or unit on each side thereof, said first and second connecting means being operable for holding the natural vertebrae on each side of the gap in fixed relation to the unit, or adjacent unit of the series of interconnected units, of said appliance.

2. A prosthetic appliance according to claim 1 wherein the or each element having a stem-portion is Y-shaped, said trough being defined by the arms of the Y, and the or each other element forms a body element (as defined hereinbefore) of the or each unit.

3. A prosthetic appliance for insertion into the gap left in the spinal column of a higher vertebrate following removal of one or more natural vertebrae therefrom, comprising a prosthetic unit for each removed natural vertebra, the or each said unit comprising a body element (as defined hereinbefore) hav-

ing a substantially flat surface that has a substantially semi-cylindrical trough extending thereacross, a substantially Y-shaped element having a stem-portion emerging at one extremity into divergent leg-portions for fastening on to the surface portions of the body element of the same unit on opposite sides of the trough to cooperate with the body element in defining a passage for the loose reception therein of said vertebrate's spinal cord, first connecting means attached to the stem-portion of the Y-shaped element or to the stem-portions of the Y-shaped elements of the end units of an interconnected series thereof for attachment to the neural spine of the natural vertebrae adjacent the gap, and second connecting means attached to the body element, or to the body elements of the end units of said series thereoffi, for attachment to the centrum of the adjacent natural vertebrae or vertebra, said first and second connecting means being cooperable with one another for holding the natural vertebra on each side of the gap in fixed relation to the units of said series thereof, for attachment connected units, of said appliance.

4. A prosthetic appliance according to claim 2 or claim 3, in which a single prosthetic unit is employed of a length adapted to fit in the gap left after removal of a single nautral vertebra, the first connecting means comprises a brace member attached intermediate the ends thereof to the stem-portion of the Y-shaped element with its extremities extending longitudinally therebeyond into position for attachment to the neural spines of the two natural vertebrae defining said gap, and in which the second connecting means comprises a pair of longitudinally-extending transversely-spaced ears projecting from both ends of the body element for reception alongside the centra of the adjacent natural vertebrae.

5. A prosthetic appliance according to claim 2 or claim 3 in which two prosthetic units are disposed in end-to-end relation to fit within the gap left after removal of two adjacent natural vertebrae, and in which a third connecting means is carried by one of the two units for connecting said one unit to the other unit to limit relative pivotal movement therebetween.

6. A prosthetic appliance according to claim 2 or claim 3 in which at least three prosthetic units are disposed in end-to-end relation to fit within the gap left after removal of a corresponding number of adjacent natural vertebrae, and in which third connecting means operatively interconnect each of the intermediate prosthetic units with the adjacent prosthetic units on both ends thereof for pivotal movement about substantially parallel axes.

7. A prosthetic appliance according to any preceding claim in which the first connecting means comprises a pair of rigid braces fastened to opposite faces of the stem-portion of said unit or each said end unit and which project longitudinally therefrom in spaced substantially parallel relation to one another for engagement with the neural spine of the adjacent natural vertebrae.

8. A prosthetic appliance according to claim 5 in which at least one longitudinally-slotted rigid brace is connected between the stem-portions of the two Y-shaped elements, said brace cooperating with said first and second connecting means to limit the extent of relative pivotal movement between the units.

9. A prosthetic appliance according to claim 5 in which the two body elements of the prosthetic units include elongate sockets in their adjacent ends arranged in aligned opposed relation and generally parallel to and spaced from the semi-cylindrical trough, and in which an elongate spring-member is positioned within the sockets bridging between the body elements, said spring member normally biasing said body elements into straight-line relation.

10. A prosthetic appliance according to claim 6 in which at least one longitudinally-extending rigid brace is attached intermediate the ends thereof to the stem-portion of the Y-shaped element mounted upon one of the intermediate body elements, the extremities of said brace extending longitudinally therefrom in opposite directions into position for attachment to the stem-portions of the Y-shaped elements adjacent the ends thereof, each of said brace extremities having a longitudinally-extending slot therein, and in which fasteners mounted within the slots attach said brace extremities to the corresponding stem-portions so as to permit relative sliding movement therebetween as the units are pivoted about their parallel axes.

11. A proesthetic appliance according to claim 6, in which the or each of the intermediate body elements of a series of at least three units has a longitudinal opening therethrough generally parallel to and spaced from the semi-cylindrical trough, the openings being aligned in relation to one another if there is more than one intermediate unit, both of the end body elements include elongate sockets arranged in opposed aligned relation to the opening or openings in the intermediate body element or elements; and in which an elongate spring member is located within the opening or openings in the intermediate body element or elements with the extremities thereof extending into the sockets in the end body elements, said spring member normally biasing said body elements into straight-line relation.

12. A prosthetic appliance according to claim 9 in which the spring member interconnects the two prosthetic units so as to

leave a gap therebetween when they are arranged in straight-line relation to one another; and in which, the sockets are shaped to immediately flex the spring member upon an application of forces to the body elements adapted to open the gap therebetween while allowing said gap to close without flexing the spring member.

13. A prosthetic appliance substantially as herein described with reference to any one of the embodiments illustrated in the accompanying drawings.

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1243353 COMPLETE SPECIFICATION

1 SHEET *This drawing is a reproduction of the Original on a reduced scale*

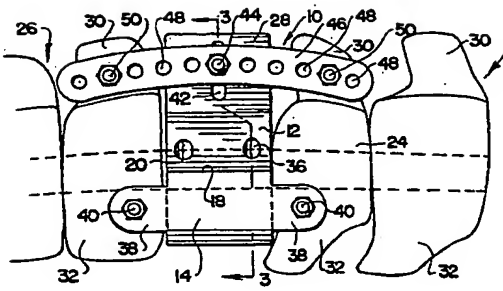

FIG. 1.

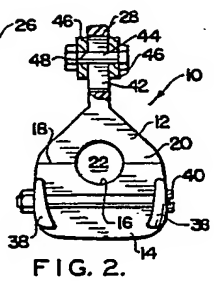

FIG. 2.

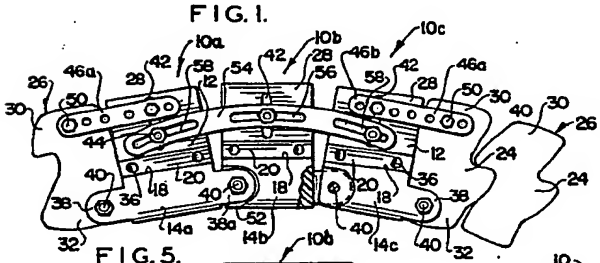

FIG. 5.

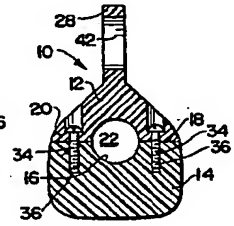

FIG. 3.

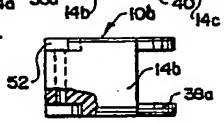

FIG. 6.

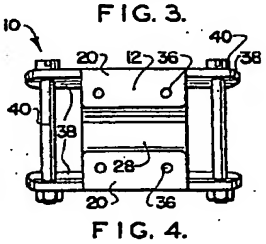

FIG. 4.

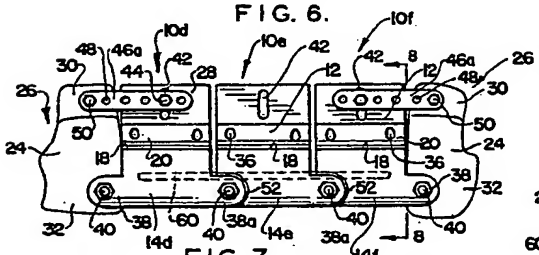

FIG. 7.

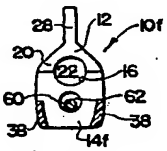

FIG. 8.

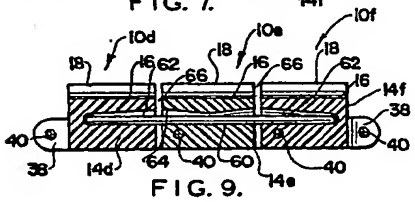

FIG. 9.